

IN THE SPECIFICATION:

On page 1, above line 1, please insert the following paragraph:

--CROSS REFERENCE TO RELATED APPLICATIONS

Applicant claims priority under 35 U.S.C. §119 of Austrian Applications Nos. A1492/2002 filed on OCTOBER 2, 2002 and Austrian A842/2003 May 30, 2003. Applicant also claims priority under 35 U.S.C. §365 of PCT/AT2003/000287 filed on SEPTEMBER 29, 2003. The international application under PCT article 21(2) was not published in English.--

On the same page, please replace the first paragraph with the following:

--The invention relates to a holding device with a ~~longitudinal, outer~~ holding container for a holding vessel, in particular a blood sample collecting tube, in which the holding container surrounds a holding chamber with a container wall, and in the direction of a longitudinal axis comprises a proximal and distal end spaced apart from one another, ~~and~~ whereby the container wall is delimited by an inner surface facing the holding chamber and an outer surface facing away therefrom, with a needle holder for a needle arrangement that can be mounted therein, in particular a double-ended cannula needle, whereby the needle holder in the holding chamber of the holding container is designed to be displaceable relative to the latter as required from a position of use in the region of the proximal end to a disposal position in the direction of the distal end, with a first adjusting device for the needle holder for the required displacement from the position of use to the disposal position,

with a cover element for the needle arrangement which can be mounted on the needle holder in the disposal position of the needle holder and with a releasable locking device.--

On the same page, following the first paragraph, please insert the following paragraphs:

--A device for collecting blood is known from WO 01/93924 A1, which comprises a holding container with a container wall, wherein the container wall surrounds a holding chamber and in the direction of a longitudinal axis has spaced apart ends. At the end of the holding container facing the patient for blood collection a needle holder with a needle arrangement mountable thereon, in particular a double-ended cannula, is provided. In addition, an adjusting device for the displacement from its position of use into the disposal position is assigned to the needle holder. A spring designed locking arm with a locking element arranged thereon is connected to the needle holder, which forms a locking device in cooperation with a locking recess in the container wall. In addition, a guide arrangement is provided between the needle holder and the container wall, by means of which during the relative displacement between the needle holder and the holding container, there can be a deflection from the straight movement of the needle holder inside the holding chamber and in this way an oblique position of the needle arrangement is achieved in the disposal position relative to the holding container. At the end facing away from the patient the holding container has an insertion element with a circular peripheral wall section, which in the disposal position covers an end of the needle arrangement facing the latter. In addition, in the disposal position in the region of the guide arrangement between the needle holder and the holding container in both movement directions at least one stop element can be arranged, in order to

secure the needle holder and the needle arrangement located in the disposal position inside the holding container.

--A further holding device with a holding container for a blood collecting tube is known from WO 92/20281 A1 in which the holding container surrounds a holding chamber with its container wall and in the direction of the longitudinal axis has spaced apart ends. Furthermore, the holding device comprises a needle holder displaceable from the position of use into the disposal position with a double-ended needle arrangement mounted therein. In the position of use the needle holder is located inside the holding chamber at the end of the holding device facing the patient, whereby one end of the needle projects out of the holding device and the other end projects over the needle holder in the direction of the holding chamber. In the container wall of the holding container in longitudinal extension thereof a slot-like recess is provided which is penetrated by a grip element connected to the needle holder, and the container wall projects to the side facing away from the holding container. The longitudinal, slot-like recess in the container wall also comprises several recesses arranged at right angles to its longitudinal extension, which are provided for interacting with the grip element in the various positions of the needle holder relative to the holding container and form a locking device. In the position of use of the needle holder one part of the grip element engages in one of these transverse recesses, whereby the needle holder together with the needle arrangement is held in position relative to the holding container. By means of the corresponding activation of the grip element the if necessary releasable locking device is released, and the needle holder can be pushed manually relative to the holding container into its disposal position. After a predeterminable displacement path of the needle holder both ends of the double-ended cannula are

located inside the holding chamber, and there is a further engagement of the grip element in one of the aforementioned transverse recesses. Afterwards, an arc-shaped part of the grip element can be pivoted inwards by a further recess in the direction of the holding chamber, whereby a cover can be obtained between one end of the double-ended cannula and the open end region of the holding container.

--A different holding device with a holding container for a blood sample collecting tube is known from WO 99/23947 A1, in which the holding container with its container wall surrounds a holding chamber and in the direction of a longitudinal axis has spaced apart ends. At the end facing the patient for collecting blood a double-ended needle arrangement is mounted in the direction of the longitudinal axis to be displaceable from its position of use into a disposal position. In the position of use one end of the double-ended needle arrangement projects over the holding container of the holding device into the side facing away from the holding chamber. Furthermore, the adjustable needle arrangement is allocated an adjusting device in the form of a spring element by means of which the needle arrangement is preloaded in the position of use by means of an if necessary releasable locking device. After the release of the locking device due to the spring adjusting device the needle arrangement is displaced relative to the holding container into the holding chamber of the holding container, whereby neither end of the double-ended cannula is freely accessible. The end of the double-ended cannula facing the holding chamber is also surrounded by a penetrable protective sleeve.

Same page, line 14, to page 2, line 10, replace this paragraph with the following:

--From US 5,810,775 A a holding device for medical blood sample collecting tubes is known, in which by means of a pivot movement of the closing element relative to the holding container an adjustment element ~~arrangement~~ arranged in its holding chamber is adjusted by adjustment elements provided on the closing element in the direction of the longitudinal axis towards the proximal end, whereby the needle holder mounted in the region of the proximal end is released from its locked position in the adjustment element and after its release is returned by a preloaded spring element into the inner chamber of the holding device together with the needle arrangement. Because of the pivotal movement of the closing element in this embodiment there is, on the one hand, a longitudinal ~~adjustment~~ displacement of the adjusting element in the direction of the longitudinal axis, and, on the other hand, after releasing or unlocking the needle holder from the adjustment element the inner chamber of the holding device is sealed, whereby the operator is prevented from coming into contact with the needle arrangement. The disadvantage of this embodiment is that the connection between the needle holder and the adjusting element in the form of a locking fit is very expensive and has to be carried out precisely, in order, on the one hand, to obtain ~~sufficient locking~~ adequate fit for the collection process, and, on the other hand, to make sure the necessary releasing force for unlocking the connection is not too great. In addition, due to the spring preloading of the needle holder, if there is an unintentional release of the locked connection between the needle holder and the ~~adjustment~~ adjusting element, caused by the rapid return of the needle into the inner chamber, there is a high risk of injury to the user of this holding device.--

Page 2, lines 11 to 21, replace this paragraph with the following:

--A further holding device for blood collecting devices is known from US 5,769,826 A or WO 98/41249 A1, in which a needle holder preloaded by a spring is held locked in the holding container by a slide in the position of use, and after the correctly performed collection procedure the lock between the slide and the needle holder can be released, whereby the latter is returned due to ~~the~~ spring preloading with the needle arrangement into the inner chamber of the holding device. The distal end of said holding device is designed to be closable as necessary by a sealing element arranged pivotably on the holding container. The disadvantage here is that on activating the slide and the restoring movement associated therewith, due to the force of the spring preloading there is a return ~~adjustment~~ displacement of the needle holder into the inner chamber, whereby if the cap or sealing element is not closed operating personnel are at risk of needle sticks.--

Same page, line 22, to page 3, line 13, replace this paragraph with the following:

--From the patent US 5,407,436 A and WO 93/23098 A1 a holding container is known with a holding device for a needle holder and a double needle inserted therein, in which the needle holder equipped with the double needle can be retracted automatically into the inside of the holding container of the holding device after releasing a retaining device into the holding chamber. The needle holder is hereby fixed by securing elements at one end of the holding container, whereby between the front end and the needle holder a compressed and thus preloaded spring is arranged, which exerts force ~~running~~ parallel to the longitudinal axis of the holding container onto the needle holder. By means of this force the needle holder is pressed against the holding catches of several securing elements. The

securing elements are designed as finger-like projections of the holding container ~~running~~ parallel to the middle longitudinal axis, and are arranged in such a way that they surround a disc-like shaped part of the needle holder over its circumference, and their holding catches aligned inwards in the direction of the middle longitudinal axis project, so far over the edge of the disc-shaped part of the needle holder, that the latter is secured against the effect of the spring. In order to trigger the automatic ~~return~~ retraction of the needle a tube-like plunger is used, which at the end to be inserted into the holding container of the holding device has an outwards pointing truncated-cone shaped tapering ~~part~~. If said plunger is pushed so far into the holding device that the truncated-cone shaped tapering is in contact with the holding catches, the securing elements with the holding catches are pressed apart to the side pointing away from the longitudinal axis, whereby the needle holder is released and displaced due to the spring force into the holding chamber. The disadvantage of this is that a separate component is needed for the release and single-handed operation is therefore not possible.--

Page 4, line 16, to page 5, line 6, replace this paragraph with the following:

--The objective of the invention is achieved in that the cover element is formed by an approximately disc-shaped main body arranged in a plane that is perpendicular to the longitudinal axis, whereby the cover element is arranged in the position of use of the needle holder adjacent to the latter on the side in the holding chamber ~~pointing away~~ averted from the proximal end, and ~~is held by a~~ in that the releasable locking device is arranged between the cover element and the holding container, with which the cover element is held in the position of use of

the needle holder relative to the latter holding container, and in that a further adjusting device in the form of an elastically deformable spring element, in particular a compression spring, is arranged between the needle holder and the cover element, whereby on releasing the locking device the cover element is displaced adjusted relative to the needle holder in the direction of the longitudinal axis by the additional adjusting device in the direction of the distal end of the holding container. The resulting surprising advantage of this is that in this way with the smallest longitudinal extension in the direction of the longitudinal axis, on the one hand, the insertion of the blood sample collecting tube for the correct collecting procedure and the injection procedure is made possible in one end of the cannula and, on the other hand, in the disposal position an operationally reliable covering of this cannula end is made possible. Furthermore, by means of the immediately adjacent arrangement of the needle holder and the cover element inside the holding container, the entire holding device is ready for appropriate use without any need for preparative steps, and the locking device can be released by the respective operator single-handedly. This can be achieved very easily by the arrangement of the locking device on the holding container by the preloaded and locked cover element in cooperation with the also preloaded needle holder. In this way, on the one hand, the needle holder is held in position in the direction of the longitudinal axis of the holding container in its position of use and, on the other hand, after releasing the locking device the cover element by means of this additional adjusting device is arranged with simultaneous displacement of the needle holder spaced apart from the latter in the disposal position inside the holding container, and thus the automatic covering of one needle end of the needle arrangement is ensured. In this way, on the one hand, a safe operation is ensured and once the collecting procedure has been completed a



secure closure of the inner chamber by the cover element for the cannula end facing the inner chamber or the distal end is achieved. In this way unintentional access to the inner chamber and the risk of unwanted needle stick injury is prevented, whereby the risk of infection to the operator is much reduced, if not eliminated. At the same time however an inexpensive holding device is created which requires only a small number of components and at the same offers a high degree of operational safety. --

On page 5, replace the first full paragraph (lines 7 to 9) with the following:

--A further embodiment according to claim 2 is also advantageous as thereby the needle holder can also be returned safely into its disposal position even after a longer storage period, and thus a high degree of operational safety is ensured. It is also advantageous in this case that by a simple operation, in particular a single-handed operation, there is not need for additional sequences to be carried out merely due to the symmetrical release of the locking device, and thus the end of the needle arrangement designed for removal or collection, for example from the arteries or veins of a patient, can be withdrawn by the first adjusting device without further changing of position of the holding container relative to the patient. At the same time, the other end of the double-ended cannula is also covered in the region of the distal end, whereby access and thus associated needle stick injury is reliably prevented from both ends of the cannula. In this way a simple one-handed operation is possible, in which the two ends of the needle arrangement are arranged inside the holding container, and in the region of the distal end unintentional needle stick injury can be avoided. --

Same page, please delete lines 10 to 16.

Same page, please replace the third full paragraph, (lines 17 to 19) with the following paragraph:

--By means of the design according to claim 4 it is possible to arrange the needle holder between ~~both the two~~ adjusting devices, whereby the insertion of the needle holder from the larger end to the smaller end is made possible. --

On the same page, please replace the fourth full paragraph (lines 20 to 25) with the following paragraph:

--~~In According to a further design variant~~ different embodiment according to claim 5 a simple structural unit is created, inside which the needle holder can be clamped between the windings, and thus, on the one hand, there can be a precise longitudinal positioning in the direction of the longitudinal axis of the holding container, and, on the other hand, a compact structural unit ~~is~~ can be obtained. Furthermore, by means of the conically expanding additional adjusting devices the assembly of the needle holder with the adjusting device can be much simplified.--

Same page, delete lines 26 and 27.

Page 6, delete lines 1 to 9.

Same page, lines 10 to 14 replace this paragraph with the following:

--In the design according to claim 5, it is an advantage, on the one hand, that with the least there can be an unhindered

longitudinal ~~extension~~ displacement of the cover element in the direction of the longitudinal axis, ~~on the one hand, the insertion of the blood sample collecting tube for the appropriate collection procedure and the injection procedure in one end of the cannula is made reliably possible inside the holding chamber,~~ and, on the other hand, ~~in the disposal position an operationally secure covering of this cannula end is made possible.~~ at the same time the holding chamber is covered by the cover element over a large part of the cross-sectional surface.

On the same page, lines 19 to 23, replace this paragraph with the following paragraph:

--By means of the design according to claim 9, residue on the cannula needle or the protective sheath surrounding the latter can be suctioned off or removed during the relative adjustment movement between the cover element and the needle holder, and thus infection caused by spraying out of individual particles, especially body fluids such as blood or the like, can be prevented.--

On the same page, lines 24 to 28, replace this paragraph with the following paragraph:

--A design according to claim 10 is also advantageous as thereby, on the one hand, the cover element can be ~~secured~~ mounted securely and in association with this the needle holder can be secured inside the holding container, and, on the other hand, the user can perform an even release by means of the diametrically opposite locking elements. In this way the tilting of the components to be adjusted inside the holding container is also prevented.--

On page 8, please replace lines 11 and 12 with the following:

--The design according to claim 25 ensures ~~the aligned arrangement and releasing of the locking device with a perfect~~ guiding in the direction of the longitudinal axis an aligned arrangement and releasing of the locking device.

Same page, replace lines 21 to 24, with the following:

--By means of the design according to claim 28, it is possible to achieve perfect guiding between the position of use and the disposal position of the parts to be displaced inside the holding container, whereby a high degree of operational safety and thereby sufficient protection for the operating personnel is ensured.--

On page 9, please replace paragraphs 1 through 6 with the following:

--The advantage in this case is that by means of the bearing force applied by the locking elements on the guide track, the cover element is always aligned centrally to the longitudinal axis, and due to the predeterminable bearing force constant frictional ratios, provided there is a ~~consistent~~ constant surface quality, can be achieved for the entire displacement.

--Further advantageous designs of the additional guiding arrangement are characterised in claims 32 to 34, whereby for the

needle holder a predetermined, straight guiding arrangement has also been provided ~~for the needle holder~~, by means of which a secure adjustment of the latter from the position of use to the disposal position is made possible. By means of the multiple arrangement of the guiding elements a tilt-free and mainly rotationally secure longitudinal movement is ~~achieved~~ performed.--

On page 9, lines 15 to 19, replace with the following:

--By means of the further developments of the additional guide arrangement, according to claims 37 to 40, on the one hand, a precise and mainly rotationally secure longitudinal guiding of the needle holder is achieved in the region of the inner surface of the holding container, and, on the other hand, a longitudinal movement into the disposal position is ensured, so that the risk of injury to the operating personnel is much reduced.--

Page 10, lines 14 to 17, replace with the following:

--Advantageous designs and arrangements of the adjusting devices on the support element are described in claims 47 to 49, as thereby with defined positioning of the needle holder relative to the holding container, also during assembly, a simple and mainly easily assembled structural unit is created.

Same page, lines 18 to 26, replace with the following:

--Further advantageous designs of the needle holder are described in claims 50 to 52, whereby all-round continuous support for the first adjusting device with simultaneous ~~centring~~ centering of the latter relative to the needle holder can be achieved. By means of the tubular depression for the additional

adjusting device a predeterminable support position is created, whereby the needle holder is positioned between the two adjusting devices, and thus a high degree of operational safety can be achieved. Furthermore, the centring element can also be used for the oriented alignment of the needle holder for insertion into the holding container, in order to be able thus to secure the alignment of the needle arrangement to be used into the thread arrangement relative to the locking device.--

Page 11, paragraph 1, lines 1 to 4, replace with the following:

--As described in claims 53 to 54 a predefined positioning of the cannula tip, in particular the tapered section for the insertion of the needle, can be created relative to the locking device, in order to permit simple one-handed use without the risk of a ~~needle~~ stick injury caused by otherwise necessary adjustment procedures.

Same page, line 9 to 12, replace with the following:

--Further advantageous designs of the cover element and the holding container are characterised in claims 56 to 59, whereby a repeat return of the cover element into the holding chamber of the holding container is prevented, and thus an undesired ~~needle~~ stick injury can be prevented along with the associated risk of possible infection.--

Same page, line 13 to 17, replace with the following:

--In the design according to claim 60 ~~the undesirable exit~~ an undesired removal of the cover element from of the holding chamber of the holding container is prevented, whereby in cooperation with the restoring elements, ~~there is a~~ clear fixing

of position in the direction of the longitudinal axis is created. Furthermore, in this way the spring force of the adjusting devices can be increased, as ~~in this way~~ thus an undesired ~~exit removal~~ is reliably prevented.

Same page, line 18 to 20, replace with the following:

--A design as described in claim 61 is also possible, as thereby ~~in this way~~ an additional anti-rotational means for the cover element about the longitudinal axis relative to the holding container is provided.--